K140764

510(k) Summary

Liquichek Immunology Control

APR 2 5 2014

1.0 **Submitter**

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Contact Person

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RA/QA Supervisor
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Date of Summary Preparation

March 25th, 2014

2.0 **Device Identification**

Product Trade Name:	Liquichek Immunology Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Immunology Control
Bio-Rad Laboratories
Predicate 510(k) Number: K022991

4.0 **Description of Device**

Liquichek Immunology Control is prepared from defibrinated human plasma with added serum proteins, stabilizers and preservatives. This product is provided in liquid form for convenience.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

5.0 **Value Assignment**

The mean values and corresponding ±3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations

over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Immunology Control claims substantial equivalence to Liquichek Immunology Control (*K022991*). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1. Similarities and Differences between new and predicate device.

Table 2: Comparison between the predicate and new Liquichek Immunology Control

Characteristics	Predicate Device Liquichek Immunology Control (K022991)	New Device Liquichek Immunology Control
Similarities		
Product Name	Liquichek Immunology Control	Liquichek Immunology Control
Intended Use	Liquichek Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Liquichek Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.
Base Matrix	Defibrinated Human Plasma	Defibrinated Human Plasma
Form	Liquid	Liquid
Thawed and Opened Stability	30 days at 2 to 8°C Except: Beta-2-Microglobulin: 21 days at 2 to 8°C Except: Rheumatoid Factor: 5 days at 2 to 8°C	30 days at 2 to 8°C Except: Beta-2-Microglobulin: 21 days at 2 to 8°C Except: Rheumatoid Factor: 10 days at 2 to 8°C
Shelf life	-20 to -70°C until expiration	-20 to -70°C until expiration
Differences		
Thawed and Unopened Stability	All analytes: 90 days at 2 to 8°C Except: Rheumatoid Factor: 25 days at 2 to 8°C	All analytes: 45 days at 2 to 8°C Except: Beta-2-Microglobulin: 40 days at 2 to 8°C Except: Rheumatoid Factor: 10 days at 2 to 8°C
Analytes	***Contains*** ADNase B, Albumin, Alpha 1-Antitrypsin, Alpha 2-Macroglobulin, Alpha-1-Acid Glycoprotein, Antistreptolysin-O, Antithrombin III (AT III), Apolipoprotein A-I, Apolipoprotein B, Beta-2-Microglobulin, C1 Inhibitor, Ceruloplasmin, Complement C3, Complement C4, C-Reactive Protein (CRP), C-Reactive Protein (hsCRP), Cystatin C, Ferritin, Haptoglobin, Hemopexin, IgG Subclass 1, IgG Subclass 2, IgG Subclass 3, IgG Subclass 4, Immunoglobulin A, Immunoglobulin E, Immunoglobulin G, Immunoglobulin M, Kappa Light Chain, Lambda Light Chain, Lipoprotein (a), Prealbumin, Properdin Factor B, Protein Serum (Total), Retinol Binding Protein, Rheumatoid Factor, Soluble Transferrin Receptor, Total Hemolytic Complement, Transferrin **Does not contain:** Anti-CCP	***Contains*** ADNase B, Albumin, Alpha 1-Antitrypsin, Alpha 2-Macroglobulin, Alpha-1-Acid Glycoprotein, Anti-CCP, Antistreptolysin-O, Antithrombin III (AT III), Apolipoprotein A-I, Apolipoprotein B, Beta-2-Microglobulin, C1 Inhibitor, Ceruloplasmin, Complement C3, Complement C4, C-Reactive Protein (CRP), C-Reactive Protein (hsCRP), Cystatin C, Ferritin, Haptoglobin, Hemopexin, IgG Subclass 1, IgG Subclass 2, IgG Subclass 3, IgG Subclass 4, Immunoglobulin A, Immunoglobulin E, Immunoglobulin G, Immunoglobulin M, Kappa Light Chain, Lambda Light Chain, Lipoprotein (a), Prealbumin, Properdin Factor B, Protein Serum (Total), Retinol Binding Protein, Rheumatoid Factor, Soluble Transferrin Receptor, Total Hemolytic Complement, Transferrin

8.0 Statement of Supporting Data

Real time stability studies were performed to establish Thawed and Opened and Thawed and unopened stability claims. Accelerated stability studies were performed for establishing the shelf life stability. The stabilities for Liquichek Immunology Control are as follows

Thawed and Opened Stability	Beta-2-Microglobulin: 21 days at 2 to 8°C Rheumatoid Factor: 10 days at 2 to 8°C All other analytes: 30 days at 2 to 8°C
Thawed and Unopened Stability	Beta-2-Microglobulin: 40 days at 2 to 8°C Rheumatoid Factor: 10 days at 2 to 8°C All other analytes: 45 days at 2 to 8°C
Shelf Life stability:	24 months at -20 to -70°C

9.0 Conclusion

Based on the performance characteristics indicated above, Liquichek Immunology Control is substantially equivalent to the predicate device (K022991).

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

BIO-RAD LABORATORIES
SUZANNE S. PARSONS
REGULATORY AFFAIRS MANAGER
9500 JERONIMO ROAD
IRVINE CA 92618

Re: K140764
Trade/Device Name: Liquicheck Immunology Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: March 25, 2014
Received: March 27, 2014

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth A. Stafford -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140764

Device Name
Liquichek Immunology Control

Indications for Use *(Describe)*
Liquichek Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A. Stafford -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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